IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

IN RE: DIET DRUGS (PHENTERMINE/ FENFLURAMINE/DEXFENFLURAMINE) PRODUCTS LIABILITY LITIGATION	)	MDL NO. 1203
THIS DOCUMENT RELATES TO:	)	
SHEILA BROWN, et al.	)	
v.	)	CIVIL ACTION NO. 99-20593
AMERICAN HOME PRODUCTS CORPORATION	)	2:16 MD 1203

MEMORANDUM IN SUPPORT OF SEPARATE PRETRIAL ORDER NO. 9141

Bartle, J. September 18, 2013

Karen L. Clark ("Ms. Clark" or "claimant"), a class member under the Diet Drug Nationwide Class Action Settlement Agreement ("Settlement Agreement") with Wyeth,[1] seeks benefits from the AHP Settlement Trust ("Trust").[2] Based on the record developed in the show cause process, we must determine whether claimant has demonstrated a reasonable medical basis to support her claim for supplemental Matrix Compensation Benefits ("Matrix Benefits").[3]

---

1. Prior to March 11, 2002, Wyeth was known as American Home Products Corporation. In 2009, Pfizer, Inc. acquired Wyeth.

2. Larry Clark, Ms. Clark's spouse, also has submitted a derivative claim for benefits.

3. Matrix Benefits are paid according to two benefit matrices (Matrix "A" and Matrix "B"), which generally classify claimants for compensation purposes based upon the severity of their

(continued...)

To seek Matrix Benefits, a claimant must first submit a completed Green Form to the Trust. The Green Form consists of three parts. The claimant or the claimant's representative completes Part I of the Green Form. Part II is completed by the claimant's attesting physician, who must answer a series of questions concerning the claimant's medical condition that correlate to the Matrix criteria set forth in the Settlement Agreement. Finally, claimant's attorney must complete Part III if claimant is represented.

In January, 2012, claimant submitted a completed Green Form to the Trust signed by her attesting physician, Manoj R. Muttreja, M.D. Based on an echocardiogram dated September 11, 2002, Dr. Muttreja attested in Part II of Ms. Clark's Green Form that she suffered from moderate mitral regurgitation and ventricular fibrillation or sustained ventricular tachycardia which results in hemodynamic compromise. He also attested that Ms. Clark underwent surgery to repair or

---

3. (...continued)
medical conditions, their ages when they are diagnosed, and the presence of other medical conditions that also may have caused or contributed to a claimant's valvular heart disease ("VHD"). See Settlement Agreement §§ IV.B.2.b. & IV.B.2.d.(1)-(2). Matrix A-1 describes the compensation available to Diet Drug Recipients with serious VHD who took the drugs for 61 days or longer and who did not have any of the alternative causes of VHD that made the B matrices applicable. In contrast, Matrix B-1 outlines the compensation available to Diet Drug Recipients with serious VHD who were registered as having only mild mitral regurgitation by the close of the Screening Period or who took the drugs for 60 days or less or who had factors that would make it difficult for them to prove that their VHD was caused solely by the use of these Diet Drugs.

replace the aortic and/or mitral valve(s) following the use of Pondimin® and/or Redux™.[4] Based on such findings, claimant would be entitled to Matrix A-1, Level V[5] benefits in the amount of $1,102,453.[6]

In the report of claimant's echocardiogram, the reviewing cardiologist, David M. Gonzalez, M.D., noted that claimant had moderate mitral regurgitation, which he measured to be 26%. Under the definition set forth in the Settlement Agreement, moderate or greater mitral regurgitation is present where the Regurgitant Jet Area ("RJA") in any apical view is equal to or greater than 20% of the Left Atrial Area ("LAA"). See Settlement Agreement § I.22.

In March, 2012, the Trust forwarded the claim for review by Zuyue Wang, M.D., F.A.C.C., F.A.S.E., one of its auditing cardiologists. In audit, Dr. Wang concluded that there

---

4. In addition, Dr. Muttreja attested that claimant suffered from an abnormal left atrial dimension. This condition is not at issue in this claim.

5. Under the Settlement Agreement, a claimant is entitled to Level V benefits if he or she qualifies for Level III benefits and suffers from ventricular fibrillation or sustained ventricular tachycardia which results in hemodynamic compromise. See Settlement Agreement § IV.B.2.c.(5)(d). A claimant is entitled to Level III benefits if he or she suffers from "left sided valvular heart disease requiring ... [s]urgery to repair or replace the aortic and/or mitral valve(s) following the use of Pondimin® and/or Redux™." Id. § IV.B.2.c.(3)(a).

6. Ms. Clark previously was paid Seventh Amendment Category One benefits. Thus, if Ms. Clark's supplemental claim for Matrix A-1, Level V benefits is payable, she only will receive the amount that exceeds the previous payment she received. See Settlement Agreement § IV.C.3.

was no reasonable medical basis for the attesting physician's finding that claimant had moderate mitral regurgitation because her echocardiogram demonstrated only mild regurgitation.[7] In support of this conclusion, Dr. Wang explained that "[t]he RJA/LAA ratio was 18% (3.7/21). The RJA encircled should not include the area of low velocity flow." Dr. Wang also concluded that there was no reasonable medical basis for the attesting physician's finding that Ms. Clark had ventricular fibrillation or sustained ventricular tachycardia which results in hemodynamic compromise. In support of this conclusion, Dr. Wang explained, "The claimant had one episode of ventricular fibrillation requiring defribrillation [sic] X1 during bypass surgery. [S]he was taken to ICU in stable condition. There is no documented evidence of hemodynamic instability associated with [ventricular] [fibrillation]."[8]

---

7. Under the Settlement Agreement, mild mitral regurgitation is defined as "(1) either RJA/LAA ratio is more than five percent (5%) or the mitral regurgitation jet height is greater than 1 cm from the valve orifice, and (2) the RJA/LAA is less than twenty percent (20%)." Settlement Agreement § I.38.

8. Dr. Wang, however, did determine that there was a reasonable medical basis for the attesting physician's finding that Ms. Clark underwent surgery to repair or replace the aortic and/or mitral valve(s) following the use of Pondimin® and/or Redux™. In support of this conclusion, Dr. Wang explained that "[t]he claimant filled prescriptions for Pondimin and Phentermine in July, August, 1996. She underwent mitral valve repair and [coronary artery bypass graft] on 10/31/08."

Pursuant to Court Approved Procedure ("CAP") No. 11, the Consensus Expert Panel[9] subsequently reviewed Ms. Clark's claim to determine whether the audit of her claim was consistent with our decision in PTO No. 8624 (Mar. 9, 2011). The Consensus Expert Panel determined Ms. Clark's claim should not be re-audited because, "Ventricular fibrillation occurring during separation from cardiopulmonary bypass is a frequent event, rather than indicating increased medical severity as spontaneous ventricular fibrillation does. However, there is no requirement for demonstrating hemodynamic compromise with ventricular fibrillation."

Thus, based on the auditing cardiologist's findings, the Trust issued a post-audit determination that claimant was entitled only to Matrix B-1,[10] Level III benefits. Pursuant to the Rules for the Audit of Matrix Compensation Claims ("Audit Rules"), claimant contested this adverse determination.[11] In

---

9. The Consensus Expert Panel consists of three cardiologists, one designated by each of Class Counsel, the Trust, and Wyeth. See Pretrial Order ("PTO") No. 6100 (Mar. 31, 2006). We approved creation of the Consensus Expert Panel to "monitor the performance of the Auditing Cardiologists and to develop procedures for quality assurance in the Audit of Claims for Matrix Compensation Benefits." Id.

10. The Settlement Agreement requires the payment of reduced Matrix Benefits to a claimant who is diagnosed with mild mitral regurgitation by an echocardiogram, like Ms. Clark's September 11, 2002 echocardiogram here, which was performed between the commencement of Diet Drug use and the end of the Screening Period. See Settlement Agreement § IV.B.2.d.(2)(a).

11. Claims placed into audit on or before December 1, 2002 are (continued...)

contest, claimant argued that there was a reasonable medical basis for Dr. Muttreja's Green Form representation that Ms. Clark suffered from moderate mitral regurgitation and ventricular fibrillation. With respect to her level of mitral regurgitation, claimant submitted: Dr. Gonzalez's report of her echocardiogram; a March 28, 2006 letter from the Seventh Amendment Fund Administration, which indicated an RJA/LAA ratio of 26.12%; and declarations of Leon J. Frazin, M.D., F.A.C.C., and Paul W. Dlabal, M.D., F.A.C.P., F.A.C.C., F.A.H.A., each of whom reviewed claimant's echocardiogram and determined it demonstrated moderate mitral regurgitation. With respect to her ventricular fibrillation, claimant contended that she is not required to prove that ventricular fibrillation, which the auditing cardiologist found, resulted in hemodynamic compromise. In addition, Ms. Clark submitted a declaration of Robert L. Rosenthal, M.D., wherein he stated that "intraoperative ventricular fibrillation is an adverse event which harms the myocardium and results in measurable changes in cardiac enzymes and cardiac output."

Although not required to do so, the Trust forwarded the claim for a second review by the auditing cardiologist. Dr. Wang

---

11. (...continued)
governed by the Policies and Procedures for Audit and Disposition of Matrix Compensation Claims in Audit, as approved in PTO No. 2457 (May 31, 2002). Claims placed into audit after December 1, 2002 are governed by the Audit Rules, as approved in PTO No. 2807 (Mar. 26, 2003). There is no dispute that the Audit Rules contained in PTO No. 2807 apply to Ms. Clark's claim.

submitted a declaration in which she again determined that there was no reasonable medical basis for the attesting physician's representations that claimant had moderate mitral regurgitation or ventricular fibrillation or sustained ventricular tachycardia which resulted in hemodynamic compromise. Dr. Wang stated, in relevant part, that:

> 12. With regard to mitral regurgitation, at Contest, I reviewed the contest materials including the Declarations of Drs. Dlabal and Frazin. I determined that the mitral regurgitation seen on Claimant's September 11, 2002 echocardiogram of attestation is mild. First, the encircled RJA improperly included low velocity flow, which is dark blue in color, instead of green mosaic color representing true mitral regurgitation. Second, the mitral regurgitation seen on the study occurs at the end of QRS, when the mitral valve suddenly closes and pushes mitral inflow back into left atrium (i.e., back flow.) Therefore, a significant part of the mitral regurgitation seen on the study is backflow, rather than true mitral regurgitation. Finally, the continuous wave Doppler shows that mitral regurgitation occurs at the beginning of systole, and does not continue through systole. For all these reasons, I confirm that there is no reasonable medical basis to conclude that Claimant had moderate mitral regurgitation.
>
> 13. With regard to ventricular fibrillation or sustained ventricular tachycardia resulting in hemodynamic compromise, at Contest I reviewed Dr. Rosenthal's declaration and accompanying articles. According to the literature provided by Dr. Rosenthal, ventricular fibrillation after release of the aortic cross-clamp in patients undergoing cardiac surgery is reported to occur in 74% to 100% of cases. This Claimant developed

> ventricular fibrillation after the release of the aortic cross clamp for which she received a single defibrillation without recurrence. There was no documented elevation of cardiac markers or LV dysfunction requiring any additional pressors or mechanical support. Claimant's records did not document any additional episode of ventricular fibrillation. Consistent with the recommendations of the CEP, the ventricular fibrillation experienced by the Claimant when separating from the bypass pump immediately after surgery does not indicate increased medical severity beyond that which required surgery.

The Trust then issued a final post-audit determination, again denying Ms. Clark's claim. Claimant disputed this final determination and requested that the claim proceed to the show cause process established in the Settlement Agreement. See Settlement Agreement § VI.E.7.; PTO No. 2807; Audit Rule 18(c). The Trust then applied to the court for issuance of an Order to show cause why Ms. Clark's claim should be paid. On November 19, 2012, we issued an Order to show cause and referred the matter to the Special Master for further proceedings. See PTO No. 8968 (Nov. 19, 2012).

Once the matter was referred to the Special Master, the Trust submitted its statement of the case and supporting documentation. Claimant then served a response upon the Special Master. The Trust submitted a reply on March 14, 2013, and claimant submitted a sur-reply on March 29, 2013. Under the Audit Rules, it is within the Special Master's discretion to

appoint a Technical Advisor[12] to review claims after the Trust and claimant have had the opportunity to develop the Show Cause Record. See Audit Rule 30. The Special Master assigned a Technical Advisor, Gary J. Vigilante, M.D., F.A.C.C., to review the documents submitted by the Trust and claimant and to prepare a report for the court. The Show Cause Record and Technical Advisor Report are now before the court for final determination. See id. Rule 35.

The issue presented for resolution of this claim is whether claimant has met her burden in proving that there is a reasonable medical basis for the attesting physician's finding that she had moderate mitral regurgitation and suffered ventricular fibrillation. See id. Rule 24. Ultimately, if we determine that there is no reasonable medical basis for the answers in claimant's Green Form that are at issue, we must affirm the Trust's final determination and may grant such other relief as deemed appropriate. See id. Rule 38(a). If, on the other hand, we determine that there is a reasonable medical basis for the answers, we must enter an Order directing the Trust to pay the claim in accordance with the Settlement Agreement. See id. Rule 38(b).

---

12. A "[Technical] [A]dvisor's role is to act as a sounding board for the judge--helping the jurist to educate himself in the jargon and theory disclosed by the testimony and to think through the critical technical problems." Reilly v. United States, 863 F.2d 149, 158 (1st Cir. 1988). In a case such as this, where conflicting expert opinions exist, it is within the discretion of the court to appoint a Technical Advisor to aid it in resolving technical issues. Id.

In support of her claim, Ms. Clark reasserts the arguments she made in contest, namely, that there is a reasonable medical basis for Dr. Muttreja's Green Form representation that claimant had moderate mitral regurgitation and ventricular fibrillation. In addition, she submitted supplemental declarations from Dr. Frazin and Dr. Dlabal. In his supplemental declaration, Dr. Frazin stated, in pertinent part, that:

> 3. Dr. Wang claimed that "the encircled RJA improperly included low velocity flow, which is dark blue in color, instead of green mosaic color representing true mitral regurgitation." This claim is incorrect. Numerous frames show that high velocities at the Nyquist limit are immediately proximal to the mitral valve. The color code for the velocities at the Nyquist limit is greenish in appearance.
>
> 4. Dr. Wang also claimed that "a significant part of the mitral regurgitation is backflow, rather than true mitral regurgitation." This claim is also incorrect. Mitral valve backflow has velocities lower than the Nyquist limit. In this case, the moderate MR jets are high velocity jets and they are at the Nyquist limit.
>
> 5. Also, velocities observed from backflow are due to blood immediately on the left atrial side of an INTACT mitral valve being pushed away from the transducer during ventricular systole. In this case, the high velocity jets indicate an INCOMPETENT mitral valve. These high velocity jets are true regurgitant jets and they are not backflow.
>
> 6. Dr. Wang also claimed that mitral regurgitation occurred at the end of the QRS complex. That is impossible. MR occurs during systole. It cannot occur at the end of the QRS, because that

period of the cardiac cycle is still diastole.

7. Lastly, Dr. Wang claimed that MR occurred at the beginning of systole and did not continue throughout systole. It only appears that way because the continuous wave Doppler was not properly aligned with the mitral regurgitant jet. Therefore, the continuous wave Doppler cannot show that MR continued throughout systole. Nevertheless, the high velocity jets described above had to occur during systole, when the aortic valve was open and the mitral valve had attempted to close.

In his supplemental declaration, Dr. Dlabal stated, in pertinent part, that:

3. In her declaration, Dr. Wang claimed that "First, the encircled RJA improperly included low velocity flow, which is dark blue in color, instead of green mosaic color representing true mitral regurgitation." This claim is completely incorrect. True mitral regurgitation (MR) is blue, or deep blue, by color flow Doppler signal. Blue-green signal, or "mosaic" would be yet a more severe case of MR, but need not be present for the existence of MR. In each case where MR was assessed, the left atrium (LA) was more than 20% filled, often up to 50% filled, with deep blue signal indicating significant regurgitation. While some (but not all) images were "generously" traced, I excluded these or adjusted for the excess tracings in making the calculations found in my original declaration.

4. "Low velocity flow" was not included in the assessment of MR in this case. There was no low velocity flow found on the edges of the clinically significant jets. Instead, low velocity flow, where present, is faint and encompasses less than 5% of the LAA. In essence, the

Settlement Agreement and Part II of the Green Form acknowledge the existence of low velocity flow, and these authorities dispense with it by restricting the diagnostic criteria for at least mild MR to 6% RJA/LAA or greater. That all jets assessed were > than 20% effectively eliminates the possibility of including low velocity flow.

5. Secondly, Dr. Wang claimed that "... the mitral regurgitation seen on the study occurs at the end of QRS, when the mitral valve suddenly closes and pushes mitral inflow back into left atrium (i.e. back flow.)" This claim is also incorrect. The moderate to severe jets are not backflow, for the reasons described above. Further, the technician was careful to insure that the signal measured included images from at least 0.16-0.20 seconds (or more) after the onset of the QRS complex. In essence, this captures MR signal from mid-systole, when MR should be maximal, if present at all, and further excludes (early) physiologic backflow, which would occur just after the onset (not the end) of mechanical LV contraction, or about 0.06 seconds after the onset of the QRS complex. (Note, at normal heart rates, the entire QRS complex through the T-wave, i.e. ventricular contraction and relaxation, lasts only 0.34-0.43 seconds.)

6. Lastly, Dr. Wang alleged that "...the continuous wave Doppler shows that mitral regurgitation occurs at the beginning of systole, and does not continue through systole." While we can agree that there is a large "pulse" of MR in the first ½ of systole, as seen by continuous wave (CW) Doppler, this does not negate the findings above, but is rather a function of the duration of MR (months vs. years), extent of the actual lesion involving the MR, ability of the LA to dilate (this one had not, as of the time of the study) as well as the orientation of the Doppler beam by the

> technician (CW provides only an "ice pick" view of a larger signal). Clinically, CW Doppler has no bearing on the assessment of severity of MR, for which the criteria are established using color flow (CF) Doppler only (not CW Doppler); these criteria have been accepted by the Settlement Agreement and applied to the Green Form Part II as well.

In response, the Trust argues that the issue is whether there is a reasonable medical basis for the attesting physician's findings, not which party can collect more opinions. With respect to claimant's level of mitral regurgitation, the Trust contends that the auditing cardiologist reviewed claimant's echocardiogram and determined that "'a significant part of the mitral regurgitation seen on the study is backflow, rather than true mitral regurgitation.'" With respect to ventricular fibrillation, the trust reasserts that the conclusions of the Consensus Expert Panel and Dr. Wang, namely, that claimant's ventricular fibrillation occurred in connection with her mitral valve repair surgery and does not demonstrate increased medical severity.

The Technical Advisor, Dr. Vigilante, reviewed claimant's September 11, 2002 echocardiogram and concluded that there was a reasonable medical basis for the attesting physician's finding that claimant had moderate mitral regurgitation. Specifically, Dr. Vigilante determined that:

> .... Visually, mild to moderate mitral regurgitation was present. I digitized the cardiac cycles in the apical views in which the mitral regurgitant jet was best

> evaluated. This jet was mostly noted in the early and mid phases of systole and was minimal during the latter part of systole. I digitally traced and calculated the RJA and LAA. I was able to accurately planimeter the RJA in the mid-portion of systole. The largest representative RJA in the apical four chamber view was 4.5 cm2. The LAA in the apical four chamber view was 21.6 cm2. Therefore, the largest representative RJA/LAA ratio in the apical four chamber view was 21% qualifying for moderate mitral regurgitation

After reviewing the entire Show Cause Record, we find that claimant has established a reasonable medical basis for her claim. First, we find that claimant has established a reasonable medical basis for finding that her echocardiogram demonstrates moderate mitral regurgitation. In connection with her review of Ms. Clark's claim, the auditing cardiologist determined that claimant's echocardiogram demonstrated only mild mitral regurgitation because (1) the RJA measurement improperly included low velocity flow and (2) a significant part of the mitral regurgitation seen on the study is backflow, rather than true mitral regurgitation.

Ms. Clark disputed these findings. In addition to the findings of Dr. Gonzalez and the Seventh Amendment Participating Physician, each of whom found that claimant's echocardiogram demonstrated moderate mitral regurgitation with an RJA/LAA of 26%, claimant submitted declarations of Dr. Frazin and Dr. Dlabal. In their declarations, Dr. Frazin and Dr. Dlabal explained that neither low velocity flow nor backflow constituted any part of their determination that claimant had moderate mitral

regurgitation. Moreover, Dr. Vigilante reviewed claimant's echocardiogram and determined that it demonstrated moderate mitral regurgitation.[13] Thus, we find that claimant has established a reasonable medical basis for finding that her echocardiogram demonstrates moderate mitral regurgitation.

Second, we find that claimant has established a reasonable medical basis for finding that she suffered ventricular fibrillation or sustained ventricular tachycardia which results in hemodynamic compromise. We previously have rejected the Trust's argument that ventricular fibrillation must occur spontaneously to be compensable under the Settlement Agreement. Specifically, in PTO No. 8624, we held that the Trust's argument that claimant was not entitled to Level V benefits because the ventricular fibrillation she experienced was "not spontaneous, but rather 'was induced by manipulation of the heart ... during surgery'" improperly required proof of causation. Mem. in Supp. of PTO No. 8624, at 17-18 (Mar. 9, 2011); see also Mem. in Supp. of PTO No. 9072, at 8-10 (May 30, 2013).

For the foregoing reasons, we conclude that claimant has met her burden of proving that there is a reasonable medical basis for her claim. Therefore, we will reverse the Trust's denial of Ms. Clark's claim for Matrix A-1, Level V benefits and the related derivative claim submitted by her spouse.

---

13. Despite an opportunity to do so, the Trust did not submit a response to the Technical Advisor Report. See Audit Rule 34.